

REMARKS

Claims 1-5 are presently rejected under 35 USC § 112, second paragraph for indefiniteness. In response to this rejection the Applicants amend claims 1 and 2 to reference a "compound" instead of a "composition". In addition, claims 3 and 4 are canceled without prejudice. Further, claim 5 is amended to reference a method of synthesizing "gabapentin tannate". After considering these amendments it is believed the Examiner will agree that claims 1, 2 and 5 now meet all the requirements of 35 USC § 112, second paragraph and, accordingly, this rejection should be withdrawn.

Turning now to the substantive issues, claims 1, 2 and 5-21 also clearly patentably distinguish over U.S. Patent 4,024,175 to Satzinger et al. when considered in combination with the Gould reference. In formulating the rejection the Examiner notes that the Satzinger et al. reference discloses the preparation of gabapentin and pharmacological compatible salts thereof. However, it is explicitly noted by the Examiner that the Satzinger et al. reference does not disclose the preparation of gabapentin tannate.

In order to address this shortcoming of the Satzinger et al. reference, the Examiner relies upon the Gould reference. On page 202 of the Gould reference, tannate is identified as an FDA-approved commercially marketed salt. The Examiner then argues that it would have been obvious for one skilled in the art to combine the Satzinger et al. and Gould teachings and produce gabapentin tannate.

The drug industry is well recognized as being one of the largest and most commercially competitive in the world. Drug companies have massive research budgets committed to the identification and development of new drugs. The pressure on those skilled in this art to produce new and alternative drugs is endless.

Significantly, it must be noted in this instance that the Satzinger et al. patent issued on May 17, 1977. That is over 27 years ago. Further, the Gould reference was published in 1986, about 18 years ago. This means that those skilled in the art have had the teachings of the Satzinger et al. and Gould references before them for approximately 18 years. However, the Examiner has failed to find or cite any reference indicating that anyone other than the present inventors have made gabapentin tannate. When this failure of others to prepare gabapentin tannate is considered in conjunction with both the passage of 18 years and the significant marketplace pressures to produce new pharmaceutical products, it is clearly disingenuous for the Examiner to argue that the present invention is obvious.

Stated another way, the development of the present invention only after the passage of 18 years in one of the most competitive product markets known to the world evidences the unobviousness and patentability of the present invention. Thus, the rejection of claims 1, 2 and 5-21 under 35 USC § 103 should fail and the claims of the present application should be allowed.

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In summary, all the pending claims meet the formal and substantive requirements of the patent laws and are in condition for formal allowance. Upon careful review and consideration it is believed the Examiner will agree with this proposition. Accordingly, the early issuance of a formal Notice of Allowance is earnestly solicited.

Respectfully submitted,

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Date Dec. 2, 2004 S. Williams